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breakfast with food and at least 8 ounces of water and at dinner with food and at least 8 ounces of water.

The patients were asked to evaluate abdominal discomfort upon waking in the morning, using a 5-point scale (Score: 0=absent, 1=mild, 2=moderate, 3=severe, 4=very severe) at 2 and 4 weeks after the initiation of the treatments.

Results

As shown in Table 2, test substance of this invention significantly improved the abdominal discomfort in patients with constipation.

TABLE 2

Effect of test substance on abdominal discomfort in patients with constipation		
Abdominal discomfort score, Mean \pm SD (N)		
	Placebo	Test Substance
Week 2	1.41 \pm 1.035 (122)	1.09 \pm 1.047* (116)
Week 3	1.64 \pm 1.114 (122)	1.27 \pm 1.057* (117)
Week 4	1.52 \pm 1.038 (122)	1.22 \pm 1.060* (117)

Test substance: 13,14-dihydro-15-keto-16,16-difluoro-PGE₁

*p < 0.05 (van Elteren test stratified by center)

EXAMPLE 3

Methods

Patients with irritable bowel syndrome (IBS) were randomly allocated to the following two treatment groups.

Group 1: Test substance (13,14-dihydro-15-keto-16,16-difluoro-PGE₁) 48 μ g total (24 μ g/breakfast+24 μ g/dinner)

Group 2: Matching placebo (placebo/breakfast+placebo/dinner)

Each group underwent two weeks washout period and then began to administer oral test substance (capsules) or placebo (capsules) daily for 4 weeks. Test substance or placebo was taken two times a day (b.i.d) at breakfast with food and at least 8 ounces of water and at dinner with food and at least 8 ounces of water. The patients were asked to evaluate abdominal bloating upon waking in the morning, using a 5-point scale (Score: 0=absent, 1=mild, 2=moderate, 3=severe, 4=very severe) at 4 weeks after the initiation of the treatments.

Results

As shown in Table 3, test substance of this invention significantly improved the abdominal bloating in patients with IBS.

TABLE 3

Effect of test substance on abdominal bloating in patients with IBS		
Abdominal bloating score, Mean \pm SD (N)		
Week	Placebo	Test Substance
Baseline	2.46 \pm 0.859 (26)	2.50 \pm 0.916 (32)
Week 4	2.42 \pm 0.945 (26)	1.74 \pm 0.999** (31)

Test substance: 13,14-dihydro-15-keto-16,16-difluoro-PGE₁

**p < 0.01 (van Elteren test stratified by center)

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EXAMPLE 4

Methods

Patients with irritable bowel syndrome (IBS) exhibiting dyschezia were randomly allocated to the following two treatment groups.

Group 1: Test substance (13,14-dihydro-15-keto-16,16-difluoro-PGE₁) 48 μ g total (24 μ g/breakfast+24 μ g/dinner)

Group 2: Matching placebo (placebo/breakfast+placebo/dinner)

Each group underwent two weeks washout period and then began to administer oral test substance (capsules) or placebo (capsules) daily for 4 weeks. Test substance or placebo was taken two times a day (b.i.d) at breakfast with food and at least 8 ounces of water and at dinner with food and at least 8 ounces of water. After 3 consecutive days of not having spontaneous bowel movement, the investigator could prescribe to the patient 10 mg bisacodyl suppository as a rescue medication. If this was not effective, Fleet® enema could be used. During the study period, each patient documented bowel activity. A spontaneous bowel movement was defined as any bowel movement except for that occurred within 24 hours after the rescue medication. Frequency of spontaneous bowel movements at Baseline, Weeks 1, 2, 3 and 4 were analyzed.

Results

As shown in Table 4, test substance of this invention significantly improved the spontaneous bowel movement frequency in patients with IBS exhibiting dyschezia.

TABLE 4

Effect of test substance on spontaneous bowel movement frequency rates in patients with IBS exhibiting dyschezia		
Spontaneous Bowel Movement Frequency Rates, Mean \pm SD (N)		
Week	Placebo	Test Substance
Baseline	1.85 \pm 2.310 (26)	1.43 \pm 0.773 (32)
Week 1	3.58 \pm 2.887 (26)	6.50 \pm 4.108** (32)
Week 2	2.84 \pm 2.481 (26)	5.58 \pm 4.003** (32)
Week 3	2.30 \pm 2.170 (26)	5.93 \pm 4.775** (32)
Week 4	2.21 \pm 2.399 (26)	5.17 \pm 4.333* (32)

Test substance: 13,14-dihydro-15-keto-16,16-difluoro-PGE₁

*p < 0.05, ** p < 0.01 (van Elteren test stratified by center)

What is claimed is:

1. A method for treating irritable bowel syndrome in a mammalian subject, which comprises administering an effective amount of 13,14-dihydro-15-keto-16,16-difluoro-18-methyl-prostaglandin E₁, or a salt, ether, ester or amide thereof, to the subject.

2. The method as described in claim 1, which comprises administering an effective amount of 13,14-dihydro-15-keto-16,16-difluoro-18-methyl-prostaglandin E₁, or a pharmaceutically acceptable salt, ester or amide thereof.

3. The method as described in claim 1, which comprises systemic administration 1-4 times per day or continuous administration in the amount of 0.01-100 μ g/kg per day or a 13,14-dihydro-15-keto-16,16-difluoro-18-methyl-prostaglandin E₁ compound.

4. A method for treating as described in claim 2, wherein the administration is in the amount of 0.1-10 μ g/kg per day.